REMARKS

Applicants would like to thank the examiner for extending the courtesy of a personal interview on March 15, 2004. During the interview, it was agreed that neither the '550 patent to Teitelbaum nor the EP '620 publication would anticipate or render obvious the claimed invention, provided that the pending claims be amended to recite that the mixture of polypeptides is non-uniform with respect to molecular weight and constitution. Applicants herein amend claim 20, the sole independent claim, and set forth below the inherent support in the specification for the amendment. In view of the amendment, the term "polydisperse" is now redundant and therefore unnecessary, it has therefore been deleted from the claims.

In addition, filed concurrently herewith is a terminal disclaimer to obviate possible obviousness-type double patenting rejections over prior patents. In accordance with the examiner's suggestion, we have included in the disclaimer all of Teva's issued U.S. patents in this family, i.e., 5.800.808, 5.981.589, 6.048.898, 6.054.430, 6.342.476, 6.362.161, and 6.620.847.

Claims 20-32 are pending in the application. Claim 20 has been amended to further clarify that the mixture is non-uniform with respect to both molecular weight and constitution. Support for the recitation "wherein the mixture of polypeptides is non-uniform with respect to molecular weight and constitution" can be found throughout the specification. For example, col. 1, l. 49-51, recites an embodiment having over 75% of its molar fraction within the molecular weight range from about 2-20 kDa. This shows that a preferred composition contains polypeptide species of non-uniform molecular weight. The molecular weight distributions shown in Figs. 1 and 2 further evidence that the polypeptide species in this mixture are of non-uniform molecular weight.

It is also readily apparent to one of ordinary skill in the art that embodiments of the invention include polypeptide species of non-uniform constitution. Copolymer-1 batches were prepared by chemically polymerizing alanine, glutamic acid, lysine, and tyrosine. Col. 1, ll. 36-41. After reading the specification, one of ordinary skill in the art would understand, based on the disclosed method of preparation, that the polypeptides in the copolymer-1 batches are of non-uniform constitution. In Example 1, for instance, "[t]wo batches of copolymer-1 were prepared

according to the methods known in the art, for example, U.S. Pat. No. 3,849,550." Col. 2, ll. 55-58. EP application 0 383 620 explicitly notes that the synthesis of copolymer-1 according to the '550 patent produces polypeptides that are non-uniform in constitution: "Although the resulting polypeptides are comprised of the same amino acid components, they differ with respect to their amino acid sequences." EP '620, p. 2, ll. 19-21.

The phrase "non-uniform with respect to molecular weight and constitution" may be used in the claims even if that phrase is not expressly stated in the specification because claim language does not require *ipsis verbis* support in the specification. "Instead, the disclosure need only reasonably convey to persons skilled in the art that the inventor had possession of the subject matter in question." Fujikawa v. Wattanasin, 93 F.3d 1559, 1570 (Fed. Cir. 1996); *see also* Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1565 (Fed. Cir. 1991) (holding that drawings alone may provide a "written description" of the invention). Therefore, because the recited phrase "non-uniform with respect to molecular weight and constitution" is clearly supported by the specification, this phrase has written description support under 35 U.S.C. § 112, first paragraph.

Applicants believe that all of the pending claims are in condition for allowance. Any questions should be directed to the undersigned at the telephone number listed below.

Respectfully submitted,

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